

Whole Food Supplements

August 24, 2000

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The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

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This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyr Wisconsin 53156-0904, is making the following statements:

- (1) The nutrients in Ligaplex II can help encourage healthy connective tissue durability—especially during periods of strenuous athletic stress, providing long-term tissue support for athletes whose joints endure frequent, repetitive activity.
- (2) The nutritional compunds found in Ligaplex II support proper formation and maintenance of skeletal tissues.
- (3) Carbamide promotes the consistent presence of healthy fluid levels in tissues in and around joints.

These statements are made for a dietary supplement containing a proprietary blend of nutritional yeast, carbamide, bovine bone, veal bone PMGTM extract, magnesium citrate, oat flour, inositol, carrot (root), dried pea (vine) juice, Tillandsia usenoides, ribonucleic acid, beet (root), bovine spleen, ovine spleen, bovine adrenal Cytosol TM extract, bovine kidney, mushroom, bovine liver fat extract, flaxseed oil extract, potassium para-aminobenzoate, rice (bran), and soy bean lecithin. Other ingredients include manganese glycerophosphate, gelatin, calcium lactate, water, calcium stearate, natural colors, mixed tocopherols, ascorbic acid, vitamin A palmitate, cellulose, cyanocobalamin, and cholicalciferol. The name of the product is Ligaplex® II.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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